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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/631,318

07/31/2003

Marvin J. Slepian

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06/24/2004

Timothy J. Oyer, Ph.D.
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EXAMINER

BOCKELMAN, MARK

ART UNIT

PAPER NUMBER

3762

DATE MAILED: 06/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/631,318

Applicant(s)

SLEPIAN ET AL.

Examiner

Mark W Bockelman

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10-16-2003</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

This application discloses and claims only subject matter disclosed in prior Application No. PCT/US89/03593, filed August 23, 1989, and names an inventor or inventors named in the prior application. It is noted that claimed prior application 07/651,346 appears to be a rule 371 application of the stated PCT. The examiner suggests applicant review the chain of priority listed in patent number 6,699,272 as the prior benefit may remove references applied against the claims.

Accordingly, this application may constitute a continuation or division. Should applicant desire to obtain the benefit of the filing date of the prior application, attention is directed to 35 U.S.C. 120 and 37 CFR 1.78.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 2-9, 12-17, 28, 30, 32, 37-42 are rejected under 35 U.S.C. 102(e) as being anticipated by Spears USPN 5,092,841.

Spears teaches the application of various prepolymeric materials including soluable polymers such as albumin that are crosslinked either by thermal energy or other known crosslinking and polymerizing techniques such as chemical polymerization. (See column 6 line 65) so as to form linings on arterial walls. The prepolymeric material may be heated and cooled (see column 10 lines 5-15) and is placed by a balloon that mechanically deforms the material to fit into cracks and fissures. (column 5 lines 40-46). Radiation may be used for heating (column 12 lines 35-44). The therapeutic agents include growth factors, antithrombotic agents (heparin), thrombolytic agents (column 7 lines 22-34) as well as alkylating, anti-proliferative agents (column 8 lines 22-34)and anti-inflammatory agents (steriodal and nonsteroidal) and monoclonal antibodies) (column 7 lines 28-34).

Claims 2, 6, 9, 14, 37, 40, 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Polin USPN 3,949,068. Polin teaches the injection of monomers and drugs into tissue for providing polymerized drug eluting structures inside the body which includes natural proteins and various pain (anti- inflamamatory) compounds. The materials will inherently modulate the tissue by providing a barrier and providing drug delivery.

Claims 2, 6, 10, 14-15, 40- 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Hettinger, Jr USPN 4,371,519. Hettinger, Jr teaches a method of injecting monomers into tissue and exemplifies embodiments that modulate the influx of oxyen and other nutrients into cancer tissues which would inherently modulate the tone and

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healing response. Polymerization is performed by injecting the monomer and a catalyst into the blood capillary system that feeds the tissue (column 1 lines 40-45).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10-11, 18-27, 29, 31, 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spears USPN 5,092,841. Applicant differs in the types of materials used such as the polymers or the specific species of drug genus that Spears teach useful for his stent. All of applicant's materials are well known materials for forming stent members as well as drugs for treating stenosis. Applicant's selection of materials known to be useful for treating stenosis would merely constitute an obvious design choice.

Claims 3-5, 7-8, 10-13, 15-36, 38-39 and 41 rejected under 35 U.S.C. 103(a) as being unpatentable over Polin USPN 3,949,068. As noted above, Polin teaches the use of prepolymers and drugs to form polymeric drug eluting devices that treat tissues in the body. Applicant differs in reciting polymers and drugs not taught by Polin, however the substitution of such known polymeric materials and drugs for treating various diseases would have been an obvious design choice.

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Claims 3-5, 7-9, 11-13 and 16-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hettinger, Jr USPN 4,371,519. Hettinger, like Polin, does not teaches a similar method but does not teach the particular polymer and drug materials that are deemed to be obvious design choices by the examiner for reasons stated above.

Double Patenting

Claims 2-42 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-24 of U.S. Patent No.5,575,815 and claims 1-35 of U.S. Patent No. 6,443,941. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims are merely broader in scope deleting patentable features from the patented claims, which would have been obvious to anyone of ordinary skill in the art.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark W Bockelman whose telephone number is (703)-308-2112. The examiner can normally be reached on Monday - Thursday 10-8:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MWB

June 22, 2004


MARK BOCKELMAN
PRIMARY EXAMINER